K092602

MAY 14 2010

510(k) Summary

According to the requirements Per 21 CFR §807.92, the following information is provides sufficient detail to understand the basis for a determination of substantial equivalence.

Company:	Abbott Laboratories
Division:	Abbott Diabetes Care, Inc.
Street Address:	1360 South Loop Road
City, State Zip:	Alameda, CA 94502
Telephone No:	510-749-5400
Fax No:	510-864-4791
Contact Person:	Arul Sterlin; Tel No. 510-864-4310; Fax No. 510-864-4791; arul.sterlin@abbott.com
Proprietary Name:	FreeStyle Lite Blood Glucose Test Strips
Common Name:	Reagent Test Strips
Classification Name:	Glucose Dehydrogenase, Glucose, Class II (21 CFR§ 862.1345) Product codes: NBW, LFR; Single Analyte Control Solution, Class I (21 CFR§ 862.1660) Product code: JJX
Predicate Device:	FreeStyle Lite Blood Glucose Monitoring System (K070850)
Manufacturing Site:	Establishment: Abbott Diabetes Care Inc. 1360 South Loop Rd. Alameda, CA 94502 Registration Number: 2954323 Establishment: Abbott Ireland Diabetes Care Donegal Town, Co. Donegal Donegal Town, IRELAND Donegal Registration Number: 3007031103

Description of the Device:

A chemistry change has been made to the FreeStyle Lite Blood Glucose Test Strip. The modified strip is to be marketed under the brand name, FreeStyle Lite, and is intended for use with the following Blood Glucose Monitoring Systems:

- FreeStyle Lite Blood Glucose Monitoring System
- FreeStyle Freedom Lite Blood Glucose Monitoring System

The meters and other system components contained within these systems have not been modified. Each of the aforementioned blood glucose monitoring systems are comprised of a handheld glucose meter, glucose reagent test strips, a quality control solution, a lancing device, lancets, lancing cap, and labeling for performing a blood glucose test. The intended uses and principles of operation for each of the systems remains the same as previously submitted and cleared for market entry. The systems utilize coulometric biosensor technology to quantitatively measure glucose concentration in whole blood samples. The systems are intended for self-monitoring of glucose in capillary and venous whole blood. The primary users are persons with diabetes. The systems are meant to aid in diabetes management and for healthcare professionals to aid in monitoring the effectiveness of diabetes control program. The FreeStyle Lite Blood Glucose Test Strip is an electrochemical biosensor that fits into a handheld meter. The blood sample volume is approximately 0.3 microliters (300 nanoliters), which can be obtained from the finger, upper arm, or palm. Test results display in accordance with the blood glucose meter's software algorithm (approximately 5 seconds). The internal volume of the test strip is precisely controlled, and a blood glucose result will not be displayed on the meter unless the internal sample chamber is filled. Once the measurement begins, the glucose is rapidly oxidized by the reagents that are present in the inside of the sample chamber. The electrochemical signal that results from this process depends only on the total amount of glucose present. The reagent chemistry enables electrolysis of glucose in the blood sample. A mediator molecule shuttles electrons rapidly between a glucose-oxidizing enzyme and the working electrode on the strip. The mediator is capable of reacting rapidly with both the electrode and the enzyme, resulting in a rapid reaction time and minimizing the total amount of mediator required. The small mediator load results in high accuracy at the low end of the glucose measurement range.

Description of Modifications:

The modifications to the system are comprised of changes to the blood glucose test strip which include chemistry, materials, appearance, and modification of the meter turn-on bar.

Chemistry:

The FreeStyle Lite Blood Glucose Test Strip chemistry for the new enzyme test strip is changed from GDH-PQQ with nPBI mediator (Osmium complex with n-pentyl benzimidazole ligand), to GDH-FAD with MAP mediator (ligand of mediator has changed to n-methyl pyridine). GDH-FAD does not show interference in the presence of carbohydrates such as maltose, lactose and galactose as compared with assays performed with GDH-PQQ. The n-pentyl benzimidazole

ligand of the mediator has changed to n-methyl pyridine and a new source of carbon ink is used to make the new enzyme chemistry compatible with on-market meters.

Materials:

The modified FreeStyle Lite Blood Glucose Test Strip will utilize the same materials as the current FreeStyle Lite Blood Glucose Test Strip, with the exception of the spacer tape and source of carbon. A new adhesive system is utilized as the spacer tape. The new spacer tape uses the exact same base polymer resin as the current FreeStyle Lite adhesive coupled with a different crosslinking agent. Screen printed carbon electrodes are made using DuPont carbon ink instead of Ercon carbon. All other materials in the modified FreeStyle Lite Blood Glucose Test Strip, (that is, the melinex and the silver/silver chloride ink) are exactly the same as those used in the FreeStyle Lite Test Strip, currently being marketed.

Appearance:

The physical appearance of the test strip has been changed to aid customers to distinguish visually between the new enzyme version of the product from the current on-market product.

Meter Turn On Bar:

Blood Glucose Test Strips that are branded as FreeStyle Lite will have a modified turn-on bar but will continue to require the same user interface no coding activities as those currently available in the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Abbott Diabetes Care Inc.
c/o Arul Sterlin
Regulatory Affairs Associate
1360 South Loop Road
Alameda, CA 94502

FEB - 1 2011

Re: k092602
Trade Name: Freestyle Lite Blood Glucose Monitoring System and
Freestyle Freedom Lite Blood Glucose Monitoring System.
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: NBW, LFR
Dated: May 08, 2010
Received: May 10, 2010

Dear Arul Sterlin:

This letter corrects our substantially equivalent letter of May 14, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events)

(21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K092602

Device Name: FreeStyle Lite Blood Glucose Monitoring System

Indication For Use:

The FreeStyle Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, upper arm and palm; and venous blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and it is not intended for use on neonates or arterial blood.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use X (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092602

Indication for Use

510(k) Number (if known): K092602

Device Name: FreeStyle Freedom Lite Blood Glucose Monitoring System

Indication For Use:

The FreeStyle Freedom Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, upper arm and palm; and venous blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and it is not intended for use on neonates or arterial blood.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use X (21 CFR Part 801 Subpart C)

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Division Sign-Off
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